UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK
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REGINA LEWIS,

Plaintiff,

-against-

MILES D. WHITE CEO FOR ABBOT LABORATORIES, JANET VERGIS PRESIDENT FOR ORTHO-MCNEIL JANSSEN, KIMBERLY PARK VICE PRESIDENT FOR ORTHO-MCNEIL JANSSEN, WILLIAM C. WELDON CHAIRMAN & CHIEF EXECUTIVE OFFICER FOR JOHNSON & JOHNSON, ABBOTT LABORATORIES, ORTHO-MCNEIL JANSSEN PHARMACEUTICALS, INC., JOHNSON & JOHNSON PHARMACEUTICAL,

Defendants.
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REPORT AND RECOMMENDATION

08 Civ. 7480 (SCR) (GAY)

TO THE HONORABLE STEPHEN C. ROBINSON, United States District Judge:

Plaintiff Regina Lewis ("Lewis"), proceeding *pro se*, brings this action against defendants Miles D. White, C[hief] E[executive] O[fficer] for Abbott Laboratories; Janet Vergis, President for Ortho-McNeil Janssen; Kimberly Park, Vice President for Ortho-McNeil Janssen; William C. Weldon, Chairman and Chief Executive Officer for Johnson & Johnson; Abbott Laboratories; Ortho-McNeil Janssen Pharmaceuticals, Inc.; and Johnson & Johnson Pharmaceutical. Construing plaintiff's complaint broadly, she asserts claims under New York product liability laws and invokes this Court's diversity

jurisdiction.[1] Presently before this Court are defendants'—Abbott Laboratories and Miles D. White—motion to dismiss pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure ("FRCP") for failure to state a claim. For the reasons that follow, I respectfully recommend that defendants' motion should be GRANTED.

I. BACKGROUND

The following facts are taken from plaintiff's Amended Complaint. For the purposes of the present motion to dismiss, said facts are presumed to be true.

Plaintiff, a resident of the state of New York, was a patient at St. Luke's hospital, located in Cornwall, New York. She was under the care of Dr. Renata Krymkevich. On August 9, 2006, Dr. Krymkevich forcibly administered the drug Depakote to plaintiff. Depakote is manufactured by defendant Abbott Laboratories, located in Abbott Park, Illinois. Defendant Miles D. White ("White") is the Chief Executive Officer ("CEO") of Abbott Laboratories.

On September 21, 2006, plaintiff was transferred to Rockland Psychiatric Center ("RPC"), located in Orangeburg, New York. Plaintiff continued to have drugs, including Depakote, forcibly administered to her until her release on November 17, 2006. Plaintiff

[1] In an order dated August 25, 2008, then Acting Chief Judge Loretta A. Preska foreclosed any claims plaintiff may have asserted pursuant to the Food, Drug and Cosmetic Act ("FDCA") on the grounds that the FDCA "limits enforcement of its provisions to suits brought by the United States." Lewis v. Abbott Laboratories, 08 Civ. 7480, Docket #3. She also directed that in order for plaintiff to invoke diversity of citizenship, plaintiff must allege each party's domicile. Id. In her Amended Complaint, plaintiff asserts mailing addresses for each of the named parties. The Court construes this as plaintiff alleging domiciles of different states. Furthermore, defendants Abbott Laboratories and Miles D. White do not contest diversity of citizenship in their present motion to dismiss.

contends that the purpose of said drugs was to chemically restrain her.

Plaintiff contends that Depakote causes dangerous side effects such as pancreas, liver, and kidney disease; blood disorders; hair loss; skin conditions; and brain damage. Amended Complaint ¶¶ 8, 15. She asserts that high doses of Depakote also cause Tardive Dyskinesia, a disease from which she now suffers. Id. ¶¶ 9, 13. She further states that a single dose of Depakote caused her "excruciating pelvic pain." Id. ¶ 9. Plaintiff contends that she suffers numerous other conditions as a result of taking Depakote including, but not limited to, burning urination, glaucoma, anemia, chronic nausea, restlessness, skin rashes, and weight gain. Id. ¶¶ 10, 16. Plaintiff also asserts that she suffered withdrawal symptoms for an entire year from Depakote. Id. ¶ 11. Her withdrawal symptoms included, but were not limited to, mania, tremors, catatonia, weight gain, dry mouth, impulses to kill herself, muscle stiffness and weakness, and burning eyes. Id.

On January 24, 2008, plaintiff filed a claim with Abbott Laboratories. Id. ¶ 12. She sought compensation for side effects she suffered from taking Depakote, namely weight gain, hair loss, and Tardive Dyskinesia. Id. She also sought compensation for "being exploited and used for experimental purposes with" Depakote. Id. Abbott Laboratories denied her claim on the grounds that it provides appropriate warnings to physicians regarding the drug's side effects. Id.; Plaintiff's Ex. B. Plaintiff asserts that her physicians did not disclose such warnings to her. Id. ¶ 14.

Plaintiff filed this present action on August 25, 2008. On October 16, 2008, plaintiff filed an Amended Complaint.

II. MOTION TO DISMISS STANDARD

In evaluating a motion to dismiss a complaint under FRCP 12(b)(6), this Court is "not to weigh the evidence that might be presented at a trial but merely to determine whether the complaint itself is legally sufficient." Goldman v. Belden, 754 F.2d 1059, 1067 (2d Cir. 1985). In doing so, the Court "must accept as true all of the factual allegations set out in plaintiff's complaint, draw inferences from those allegations in the light most favorable to plaintiff, and construe the complaint liberally." Gregory v. Daly, 243 F.3d 687, 691 (2d Cir. 2001). Ultimately, the Court must grant a 12(b)(6) motion to dismiss if the plaintiff fails to allege "enough facts to state a claim to relief that is plausible on its face." Bell Atlantic Corp. v. Twombly, 127 S. Ct. 1955, 1974 (2007).

For purposes of evaluating a 12(b)(6) motion, the complaint "is deemed to include any written instrument attached to it as an exhibit or any statements or documents incorporated in it by reference." Chambers v. Time Warner, Inc., 282 F.3d 147, 152-53 (2d Cir. 2002) (quotation and citation omitted). "Even where a document is not incorporated by reference, the court may nevertheless consider it where the complaint relies heavily upon its terms and effect, which renders the document integral to the complaint." Id. at 153 (quotation and citation omitted). Further, *pro se* complaints are held to "less stringent standards than formal pleadings drafted by lawyers." Haines v. Kerner, 404 U.S. 519, 520 (1972). *Pro se* complaints and supporting papers must be read "liberally" and interpreted to "raise the strongest arguments that they suggest." See Soto v. Walker, 44 F.3d 169, 173 (2d Cir. 1995) (quotation and citation omitted).

III. DISCUSSION

Reading plaintiff's complaint broadly, plaintiff appears to claim that (1) Depakote is an inherently dangerous drug; (2) Depakote's actual and potential side effects outweigh its benefits; (3) Abbott Laboratories fails to provide warnings which can be understood by lay persons; (4) there is no data to support the benefits of long-term use of Depakote, yet doctors administered said drug to plaintiff for an extended period of time; and (5) White is liable for Depakote "being sold and marketed and used in an unsafe and unreasonable manner." See Amended Complaint ¶¶ 3, 5, 8, 9, 12. As such, plaintiff asserts that she has suffered injuries as a result of taking and then withdrawing from said drug. See, e.g., Amended Complaint ¶¶ 9-11. Plaintiff's claims (1)-(4) sound of product liability claims. In claim (5), plaintiff attempts to pierce the corporate veil.

A. Product Liability

Under New York law, a plaintiff may assert product liability claims for injuries caused by an allegedly defective product under theories of negligence, strict liability, or breach of express or implied warranty. Voss v. Black & Decker Mfg. Co., 450 N.E.2d 204, 207 (N.Y. 1983). Regardless under which theory plaintiff pleads her case, the plaintiff has the burden to show that a defect in the product was a substantial factor in causing injury. Plemmons v. Steelcase Inc., No. 04 Civ. 4023, 2007 WL 950137, at *5 (S.D.N.Y. Mar. 29, 2007).[2]

[2] The Court has attached a copy of this and any other unreported decisions herein for *pro se* plaintiff's access.

1. Negligence and Strict Liability

A plaintiff may allege that a product is defective on the grounds of a (1) design defect; (2) failure to warn; or (3) manufacturing defect. Colon v. BIC USA, Inc., 199 F. Supp. 2d 53, 82-83 (S.D.N.Y. 2001). A strict products liability claim arises against a manufacturer, a retailer, or a commercial lessor of a product if (1) the product is defective, and (2) the defect caused plaintiff's injury. Id. at 82. A negligence claim requires the plaintiff to show that (1) "the manufacturer owed plaintiff a duty to exercise reasonable care;" (2) the manufacturer breached that duty by failing to use reasonable care so that the product was rendered defective; (3) "the defect was the proximate cause of the plaintiff's injury; and" (4) plaintiff suffered "loss or damage." Id.

a. Design Defect

To assert a design defect claim, a plaintiff must prove that "(1) the product as designed posed a substantial likelihood of harm; (2) it was feasible to design the product in a safer manner; and (3) the defective design was a substantial factor in causing plaintiff's injury." Id. at 83 (citing Voss, 450 N.E.2d at 207-08). New York refers to these first two prongs of the test as "the risk-utility balancing test [which is] used to determine whether a product is defective or 'unreasonably dangerous.'" Id. at 84 (citations omitted). The question is "whether after weighing the evidence and balancing the product's risks against its utility and cost, it can be concluded that the product as designed is not reasonably safe." Voss, at 208 (citation omitted). "[F]or the purposes of analyzing a design defect claim, the theories of strict liability and negligence are virtually identical." Colon, 199 F. Supp. 2d at 83 (citation omitted).

Here, plaintiff's claims that (1) Depakote is inherently dangerous and (2) its side

effects outweigh its benefits ring of design defect claims. Specifically, plaintiff contends that Depakote is an inherently dangerous drug because it causes, for example, pancreas, liver, and kidney disease; blood disorders; hair loss; skin conditions; and brain damage. Amended Complaint ¶¶ 8, 15. She also contends that the negative consequences of high doses of Depakote outweigh the benefits the drug offers. Amended Complaint ¶ 9. However, plaintiff's allegations are conclusory. Further, plaintiff has not alleged that it was feasible for Abbott Laboratories to design Depakote in a safer manner. Thus, plaintiff has not met her burden to allege evidence that Depakote is not reasonably safe. See Voss, 450 N.E.2d at 208 ("The plaintiff . . . is under an obligation to present evidence that the product, as designed, was not reasonably safe . . . .").

b. Failure to Warn

To prove a defect in the form of a failure to warn, a plaintiff must show "(1) that a manufacturer has a duty to warn; (2) against dangers resulting from foreseeable uses about which it knew or should have known; and (3) that failure to do so was the proximate cause of harm." Id. at 84. "Foreseeable uses" of which a manufacturer has a duty to warn include reasonably foreseeable unintended uses. Liriano v. Hobart Corp., 700 N.E.2d 303, 305 (N.Y. 1998) (citations omitted). The Second Circuit has stated that "a defendant's *liability* will not arise from a breach of [the] duty [to warn] alone. Instead, the plaintiff must show, in addition, that 'the failure to warn [was] a substantial cause of the events which produced the injury.'" Burke v. Spartanics Ltd., 252 F.3d 131, 139 (2d Cir.2001) (emphasis in original) (citation omitted). "Failure to warn claims are identical under strict liability and negligence theories of recovery."

Colon, 199 F. Supp. 2d at 84 (citations omitted).

Additionally, under New York law, a drug manufacturer has (a) a duty to warn the doctor, not the patient; (b) the warning must "provide sufficient information to that category of prescribing physicians who may be expected to have the least knowledge and experience with" the product; and (c) the patient must establish that the failure to give a proper warning was the proximate cause of her injuries. See Lindsay v. Ortho Pharm. Corp., 637 F.2d 87, 91 (2d Cir.1980) (citation omitted); Glucksman v. Halsey Drug Co., 553 N.Y.S.2d 724, 726 (1st Dep't 1990) (citations omitted).

In the present case, plaintiff alleges that any warning Abbott Laboratories provides regarding Depakote cannot be understood by lay persons. Amended Complaint ¶ 12. Construing plaintiff's complaint broadly, the Court perceives plaintiff also to claim that Abbott Laboratories failed to provide warnings of long-term use of Depakote. See Amended Complaint ¶ 3. However, plaintiff has not alleged that Abbott Laboratories failed to provide warnings to her doctors. Therefore, plaintiff has not alleged sufficient evidence to support a failure to warn claim. See Glucksman, 553 N.Y.S.2d at 726 (the manufacturer of a prescription drug has a duty to warn the medical community, not the patient); Lindsay, 637 F.2d at 92 (plaintiff must show that the drug manufacturer failed to give adequate warnings to her treating physicians, otherwise her claims are not actionable).

c. Manufacturing Defect

"To plead and prove a manufacturing flaw under either negligence or strict liability, the plaintiff must show that a specific product unit was defective as a result of

'some mishap in the manufacturing process itself, improper workmanship, or because defective materials were used in construction,' and that the defect was the cause of plaintiff's injury." Colon, 199 F. Supp. 2d at 85 (quoting Caprara v. Chrysler Corp., 417 N.E.2d 545, 552-53 (N.Y. 1981)). "The crux of a . . . manufacturing defect claim is the product's failure to perform as expected due to an error in the manufacturing process that resulted in a defect." Derienzo v. Trek Bicycle Corp., 376 F. Supp. 2d 537, 560 (S.D.N.Y. 2005). A plaintiff must assert that (1) the product was not reasonably safe as marketed; (2) plaintiff used the product for a normal purpose; (3) by exercising reasonable care, plaintiff would not have discovered the defect and apprehended its danger; and (4) plaintiff would not have otherwise avoided injury by exercising ordinary care. Id.

In the present case, plaintiff does not assert a manufacturing defect claim. She does not allege that the particular Depakote administered to her had a defect as compared to other Depakote. Rather, plaintiff alleges that Depakote, itself, is defective. The Court addresses plaintiff's claims therein supra and infra.

2. Breach of Implied Warranty

Establishing a breach of implied warranty claim requires that plaintiff prove: "(1) that the product was defectively designed or manufactured; (2) that the defect existed when the manufacturer delivered it to the purchaser or user; and (3) that the defect is the proximate cause of the accident." In re American Export Lines, Inc., 620 F. Supp. 490, 518 (S.D.N.Y.1985). See also Plemmons, 2007 WL 950137 at * 3. The "implied warranty is breached where the product in question is not fit for the ordinary purpose for

which it is to be used." Id. (citation omitted).

Construing plaintiff's complaint broadly, plaintiff appears to allege that Depakote is not fit for the ordinary purpose for which it is used. Specifically, plaintiff contends that although doctors administered Depakote to her for a long period of time, "no body of evidence" supports the "benefits or the safety and effectiveness of Depakote in long term use." Amended Complaint ¶ 3. In order to succeed on this claim, plaintiff must submit evidence that Depakote is a defective product. See Plemmons, 2007 WL950137, at *5 (quotation omitted) (an essential element of a claim of breach of implied warranty is the existence of a defect in the product). As discussed above, plaintiff has not pleaded necessary elements to support a design, failure to warn, or manufacturing defect claim. Therefore, plaintiff has failed to plead an essential element of her breach of implied warranty claim.

Plaintiff has failed to allege facts to support a design, failure to warn, or manufacturing defect claim; or a breach of warranty claim. Accordingly, I respectfully recommend that plaintiff's product liability claims should be dismissed.

B. Piercing the Corporate Veil

An alter ego of a corporation may be held liable for acts of said corporation "only when the corporate 'form has been so dominated by [that] individual . . . and its separate identity so disregarded, that it primarily transacted the dominator's business rather than its own and can be called the other's alter ego.'" Bridgestone/Firestone, Inc. v. Recovery Credit Servs., Inc., 98 F.3d 13, 17-18 (2d Cir. 1996) (quoting Gartner v. Snyder, 607 F.2d 582, 586 (2d Cir. 1979)). Under New York law, a court may pierce the corporate veil where (1) the alter ego "'exercised complete domination over the

corporation with respect to the transaction at issue'" and (2) "'such domination was used to commit a fraud or wrong that injured the party seeking to pierce the veil.'" MAG Portfolio Consult, GMBH v. Merlin Biomed Group LLC, 268 F.3d 58, 63 (2d Cir. 2001) (quoting Am. Fuel Corp. v. Utah Energy Dev. Co., 122 F.3d 130, 134 (2d Cir. 1997)). In determining whether to pierce the corporate veil, courts may consider such factors as:

> (1) disregard of corporate formalities; (2) inadequate capitalization; (3) intermingling of funds; (4) overlap in ownership, officers, directors, and personnel; (5) common office space, address and telephone numbers of corporate entities; (6) the degree of discretion shown by the allegedly dominated corporation; (7) whether the dealings between the entities are at arms [sic] length; (8) whether the corporations are treated as independent profit centers; (9) payment or guarantee of the corporation's debts by the dominating entity; and (10) intermingling of property between the entities.

Id. (quoting Freeman v, Complex Computing Co., 119 F.3d 1044, 1053 2d Cir. 1997).

Here, interpreting plaintiff's complaint broadly, plaintiff seeks to hold defendant White liable for selling and marketing Depakote as an "alter ego" of Abbott Laboratories. Specifically, plaintiff states that White "oversees the entire operation [of Abbott Laboratories] and therefore is responsible for the drugs being sold and marketed and used in an unsafe and unreasonable manner." Amended Complaint ¶ 5. However, plaintiff has not alleged that White exercised complete domination over Abbott Laboratories in selling or marketing Depakote. Furthermore, plaintiff has not alleged facts corresponding to any of the above-listed factors for this Court to consider. As such, plaintiff has failed to allege facts to support piercing the corporate veil. Accordingly, I respectfully recommend that plaintiff's claim against White should be dismissed.

IV. CONCLUSION

For all of the foregoing reasons, I conclude, and respectfully recommend, that defendants' motion to dismiss should be granted as to all of plaintiffs' claims against Abbott Laboratories and White.

V. NOTICE

Pursuant to 28 U.S.C. § 636(b)(1)(B), as amended, and Rule 72(b), Fed. R. Civ. P., the parties shall have ten (10) days from receipt of this Report to serve and file written objections to this Report and Recommendation. If copies of this Report are served upon the parties by mail, the parties shall have thirteen (13) days from receipt of this Report to file and serve written objections. See Fed. R. Civ. P. 6(d). Such objections, if any, shall be filed with the Clerk of the Court, with extra copies delivered to the chambers of The Honorable Stephen C. Robinson at the United States District Court, Southern District of New York, 300 Quarropas Street, White Plains, New York, 10601, and to the chambers of the undersigned at said Courthouse.

Failure to file timely objections to this Report and Recommendation will preclude later appellate review of any order of judgment that will be entered. See Caidor v. Onondaga County, 517 F.3d 601, 604 (2d Cir. 2008).

Requests for extensions of time to file objections must be made to the Honorable Stephen C. Robinson and not to the undersigned.

Dated: June 18, 2009
White Plains, New York

Respectfully Submitted:

GEORGE A. YANTHIS, U.S.M.J.